

(c) inoculating said mammalian host with said particulate polynucleotide; and,

(d) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell within said mammalian host, such that said expressed antigenic protein or antigenic protein fragment is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway, wherein said presentation of said antigenic protein or protein fragment elicits an anti-tumor or anti-viral immune response in said host that destroys neoplastic or virally infected cells.

C1
SUB P2
cont

15. (Twice amended) An *in vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

(a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;

(b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;

(c) inoculating said mammalian host with said particulate polynucleotide using a biolistic device; and,

(d) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell within said mammalian host, such that said expressed antigenic protein or antigenic protein fragment is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway, wherein said presentation of said antigenic protein or protein fragment elicits an anti-tumor or anti-viral immune response in said host that destroys neoplastic or virally infected cells.

C2

SUB D3

29. (Twice amended) An *in vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

(a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;

(b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;

(c) inoculating said mammalian host with said particulate polynucleotide by direct injection; and,

C3

SUB D4

(C3
SUB P4
cont)

(d) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell within said mammalian host, such that said expressed antigenic protein or antigenic protein fragment is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway, wherein said presentation of said antigenic protein or protein fragment elicits an anti-tumor or anti-viral immune response in said host that destroys neoplastic or virally infected cells.

44. (Twice amended) An *ex vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

(a) generating a DNA fragment which expresses an antigenic protein or antigenic protein fragment;

(b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;

(c) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell of a mammalian host *in vitro*, such that said expressed antigenic protein or antigenic protein fragment is presented on the membrane surface of said antigen presenting cell through the MHC class I pathway, [wherein said presentation of said antigenic protein or protein fragment elicits an immune response in said host]; and,

(C4
SUB P5)

(d) inoculating said mammalian host with said antigen presenting cell by direct injection, wherein presentation of said expressed antigenic protein or protein fragment on said antigen presenting cells of said hosts elicits an anti-tumor or anti-viral immune response that destroys neoplastic or virally-infected cells in said host.

59. (Thrice amended) An *ex vivo* method of treating a mammalian host capable of generating an immune response, which comprises:

(a) generating a DNA fragment which expresses a molecule which enhances the antigen presentation function of an APC;

(b) distributing said DNA fragment on a particle surface, resulting in a particulate polynucleotide;

(c) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell of a mammalian host *in vitro*, such that said antigen presentation enhancing protein is expressed; and,

(C5)

C₁₅
(d) inoculating said mammalian host with said antigen presenting cell by direct injection.

Please add the following new claims:

SVB E1)
-- 68. A method for transfecting an antigen presenting cell comprising:
(a) distributing a DNA fragment which expresses an antigenic protein or fragment thereof on a particle surface, resulting in a particulate polynucleotide;
(b) delivering said particulate polynucleotide to the cytoplasm of an antigen presenting cell, such that said expressed antigenic protein or fragment thereof is presented to the membrane surface of said antigen presenting cell.

C₆
69. The method of Claim 68, wherein said delivering step occurs *in vivo*.

70. The method of Claim 68 wherein said delivering step occurs *in vitro*.

SVB E1)
71. A method of inducing a CTL immune response in a mammalian host capable of generating an immune response, comprising the step of transfecting antigen presenting cells of said host *in vivo* with a DNA fragment which expresses an antigenic protein or fragment thereof, such that said antigenic protein or fragment thereof is presented to the membrane surface of said antigen presenting cell through the MHC class I pathway and tumor cells are destroyed. --

REMARKS

Rejections Under 35 U.S.C. § 112

Claims 1-3, 5-17, 19-32, 34-47, 49-61 and 63-67 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being enabling for the breadth of the claims. This rejection is respectfully traversed.

The Office Action states that the specification does not provide enablement for the claimed methods of providing treatment in the form of an elicited immune response in mammalian hosts afflicted with a naturally occurring disease which may evade immune system recognition. (Office Action, pp. 2-3.)